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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,236	04/19/2001	David Geraint Owen	07203.0024	6215

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 09/29/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/719,236

Applicant(s)

OWEN ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19,22-28 and 47-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19,22-28 and 47-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant's amendment filed 6/30/03 in Paper No. 16 is acknowledged and entered. Claims 20-21, 29-38, and 46 are canceled by the amendment. Claims 1, 3, 10, 23, and 26 are amended by the amendment. Claims 47-56 are added by the amendment.
2. Claims 1-19, 22-28, and 47-56 are pending.

Drawings

3. It is noted that applicant did not correct any of the informalities indicated on the attached "Notice of Draftsperson's Patent Drawing Review," PTO-948 mailed on 12/31/02 with the previous Office Action. In order to avoid abandonment of this application, correction is required in reply to the Office action. The correction will not be held in abeyance.

Specification

4. The substitute specification filed 6/30/03 is acknowledged and entered.

Withdrawn Rejections

5. The previous objection for claims 20-21 has been withdrawn in view of applicant's cancellation of claims 20-21.
6. The previous rejections 35 USC 112, second paragraph, for claims 1-28 have been withdrawn in view of applicant's amendments of claims 1, 3, 10, and 26 and cancellation of claims 20-21.

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7. The previous rejections under 35 USC 102(b) as being anticipated by Osman et al. (US Patent 5,234,566) for claims 1, 4, 6, 8, 11-12 and 19-22 have been withdrawn in view of applicant's amendments of claim 1 and argument that "[O]sman does not disclose a solution perfusion channel that is on the opposite side of the substrate from the biological membrane".

8. The previous rejections under 35 USC 102(e) as being anticipated by Kovacs et al. (US Patent 5,981,268) for claims 1, 9, 19, and 22-28 have been withdrawn in view of applicant's amendments of claims 1 and 23.

9. The previous rejections under 35 USC 103(a) as being obvious over Olesen et al. (US Patent 6,063,260) in view of Stephens et al. (*Journal of Physiology*, 1994, 477(2):187-196) for claims 1-10, 14, 18-22 have been withdrawn in view of applicant's amendments of claim 1 and argument that Olesen et al. and Stephens et al. do not teach a "perfusion channel".

10. Claims 1-19, 22-28, and 47-56 are treated on the merit in this Office Action.

Maintained Rejections

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 1, 13, and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osman et al. (US Patent 5,234,566) in view of Fare et al. (US Patent 5,225,374).

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Osman et al. disclosed a biosensor comprising at least one lipid membrane (biological membrane) each including a least one gated ion channel having a conductance, which is dependent upon an electric field applied across the membrane (col. 1, lines 49-55) (referring to claims 1, 4, 6, and 20-22). The ion channels are incorporated in the lipid membranes (col. 5, lines 6-22). In a two dimensional array, the lipid membrane is formed directly on the substrate surfaces and is directly coupled to the electrode (col. 8, lines 17-31). Wells are made over each element of the array (col. 8, lines 28-31). The substrate is made of materials such as glasses (col. 8, lines 32-35). Therefore, the biosensor of Osman et al. anticipates the presently claimed invention.

The biosensor of Osman et al. does not expressly disclose that the substrate is perforated.

Fare et al. disclose a biosensor comprising a lipid bilayer that adheres to the porous substrate forming a high impedance seal (col. 3, lines 16-20; col. 4, lines 35-47). The pore size is from 1 to 1000 nm (col. 5, lines 24-32) (referring to claims 15-17). This would provide a surface for the lipid bilayer to adheres to without defects and tears to the lipid bilayer (col. 2, lines 41-43; col. 5, lines 34-35).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a perforated substrate as taught by Fare et al. in the biosensor of Osman et al. One of ordinary skill in the art would have been motivated to include a perforated substrate in the biosensor of Osman et al. for the advantage of providing a surface for the lipid bilayer to adheres to without defects and tears to the lipid bilayer (Fare: col. 2, lines 41-43; col. 5, lines 34-35) since both Osman et al. and Fare et al. disclose a lip membrane biosensor (Osman: col. 1, lines 49-55; Fare: col. 3, lines 16-20; col. 4, lines 35-47).

Response to Arguments

13. Applicant's argument(s) directed to the above rejection under 35 USC 103(a) as being unpatentable over Osman et al. (US Patent 5,234,566) in view of Fare et al. (US Patent 5,225,374) for claims 1, 13, and 15-17 was considered but they are not persuasive for the following reasons.

Applicant contends that the combination of Osman et al. and Fare et al. is unobvious over the presently claimed invention because "[O]sman does not disclose a solution perfusion channel that is on the opposite side of the substrate from the biological membrane" and Fare et al. would not overcome the this deficiencies.

Applicant's arguments are not convincing since the combination of Osman et al. and Fare et al. is obvious over the presently claimed invention. Although Osman et al. do not disclose a "solution perfusion channel" on the opposite side of the porous substrate from the biological membrane, Fare et al. do disclose do disclose a "solution perfusion channel" on the opposite side of the porous substrate from the biological membrane (fig. 4). Thus Fare et al. do overcome the deficiencies.

Additionally the limitation of "for use in a high throughput screening process" should not be considered as limitations for this apparatus because these limitations represent functional language describing a use of the apparatus. See MPEP § 2114:

Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). (emphasis in original)

A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Therefore, the structure of the combination of Osman et al. and Fare et al. is obvious over the presently claimed structure.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 1-19, 22, and 47-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection.)

The instant apparatus claims 1, 47 and 56 briefly recite that structurally the substrate is disposed between the membrane and a solution perfusion channel.

The recitation of ‘a solution perfusion channel’ and that the “substrate is disposed between the membrane and a solution perfusion channel” as claimed in claims 1, 47, and 56, have no clear support in the specification and the claims as originally filed. The specification in paragraph [0018] disclosed that the reference # 7 of figures 1-6 refers to *‘a solution perfusion channel’* is not support for ‘a solution perfusion channel’ and that the “substrate is disposed between the membrane and a solution perfusion channel” since none of the figure discloses reference #7. Because the specification recites that the reference # 7 of figures 1-6 refers to *‘a solution perfusion channel’* and that the figures do not disclose the reference number 7, does not

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support the limitation of the claim, which recites 'a solution perfusion channel' and that the "substrate is disposed between the membrane and a solution perfusion channel". Therefore, there is no support for the limitation of 'a solution perfusion channel' and that the "substrate is disposed between the membrane and a solution perfusion channel" as originally disclosed in the specification.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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18. Claims 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olesen et al. (US Patent 6,063,260) and Kovacs et al. (US Patent 5,981,268).

Kovacs et al. disclose a biosensor comprising a layer of cells adhering to the surface of the microelectrode array on an integrated device (col. 7, lines 25-40; fig. 3) (claims 1 and 22). The biosensor monitors the activation of voltage-gated ion channels (col. 4, lines 3-7). The ion measure includes potassium and sodium (col. 14, lines 19-22). The substrate comprise of material such as glasses and polymer (col. 13, lines 20-23). The array of electrodes would also be on a substrate of multiwell plates (col. 13, lines 49-50). The activity of the cellular ion channels and the action parameters of the cell are monitor as a result of their effect on the impedance measured between each microelectrode and the reference electrode (col. 9, lines 26-29).

The apparatus of Kovacs et al. does not expressly disclose that a movable recording head.

Olsen et al. disclose a high throughput patch clamp apparatus (Abstract). The patch clamp comprise of a membrane ion channel of a cultured cell, which is position on a coverslip (col. 9, lines 57-67). The patch electrode pipette comes into contact with the membrane and a giga-seal is created between the pipette and the membrane by way of suction. An electrical signal is detected by an electrode in the patch pipette (col. 10, lines 1-2).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a movable recording head as taught by Olesen et al. in the apparatus of Kovacs et al. One of ordinary skill in the art would have been motivated to include a movable recording head in the apparatus of Kovacs et al. for the advantage of carrying out ion transfer channels study in biological membranes in a high throughput format (Olesen: col. 1,

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lines 8-21) since both Olesen et al. and Kovacs et al. disclose monitor voltage impedance from cell membrane (Olesen: col. 1, lines 8-21; Kovacs et al.; Abstract).

19. Claims 47-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al. (US Patent 5,981,268) and Fare et al. (US Patent 5,225,374).

Kovacs et al. disclose a biosensor comprising a layer of cells adhering to the surface of the microelectrode array on an integrated device (col. 7, lines 25-40; fig. 3) (claims 1 and 22). The biosensor monitors the activation of voltage-gated ion channels (col. 4, lines 3-7). The ion measure includes potassium and sodium (col. 14, lines 19-22). The substrate comprise of material such as glasses and polymer (col. 13, lines 20-23). The array of electrodes would also be on a substrate of multiwell plates (col. 13, lines 49-50). The activity of the cellular ion channels and the action parameters of the cell are monitor as a result of their effect on the impedance measured between each microelectrode and the reference electrode (col. 9, lines 26-29).

The apparatus of Kovacs et al. does not expressly disclose that the substrate is between the membrane and the solution profusion channel.

Fare et al. disclose a biosensor comprising a lipid bilayer that adheres to the porous substrate forming a high impedance seal (col. 3, lines 16-20; col. 4, lines 35-47). The pore size is from 1 to 1000 nm (col. 5, lines 24-32) (referring to claims 15-17). This would provide a surface for the lipid bilayer to adheres to without defects and tears to the lipid bilayer (col. 2, lines 41-43; col. 5, lines 34-35)

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include that the substrate is between the membrane and the solution perfusion channel as taught by Fare et al. in the apparatus of Kovacs et al. One of ordinary skill in the art would have been motivated to include that the substrate is between the membrane and the solution perfusion channel in the apparatus of Kovacs et al. for the advantage of increasing the signal to noise ratio of the receptor signal over the background noise of the sensor circuit (Fare: col. 2, lines 66-68) since both Kovacs et al. and Fare et al. disclose an apparatus that detect signal from a biological membrane (Kovacs et al.; Abstract; Fare: col. 3, lines 57-68).

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on Increased Flex Schedule and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
September 23, 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER